

Application No. 09/510,937

and col. 4, lines 55-68 of Gore, US 3,953,566 incorporated by reference into the present application (at page 7, lines 18-20).

## **II. APPLICANTS' INVENTION**

The present invention relates to a catheter balloon made of porous expanded polytetrafluoroethylene (PTFE) provided with a non-porous coating over the porous PTFE. The coating renders the balloon non-porous. The thinness, flexibility and strength of the construction allow the resulting balloon to be collapsed to a small first diameter for insertion into the vasculature to a desired location at which it can be inflated to the maximum diameter of the tube in the fashion of a conventional polyethylene terephthalate (PET) catheter balloon. The balloon of the present invention is superior to such conventional balloons again due to its flexibility, thinness, strength and lubricious materials.

## **III. REJECTION OF CLAIMS 1-9 UNDER 35 USC 112, 2<sup>nd</sup> PARAGRAPH AS BEING INDEFINITE.**

While the previous Office Action addressed the 35 CFR 102 and 103 rejections prior to the 35 USC 112 rejection, the latter rejection is being addressed first in that it relates to two amendments to claim 1.

The Examiner states that Claim 1 (and claims dependent thereto) are indefinite because "...provided with a non-porous coating..." does not identify where & how the non-porous coating is provided. He suggests that the claim be amended to recite "...provided with a non-porous coating over the porous PTFE to render the balloon non-porous." Claim 1 is amended accordingly herein.

The Examiner also states that Claim 1 is indefinite in the recitation of "a small size" and "a maximum diameter." The claim is amended herein to delete this language as unnecessary.

Finally, the present claims are directed to a catheter balloon and not to the combination of the balloon and the catheter tube or catheter shaft to which it might be affixed.

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**III. REJECTION OF CLAIMS 1-9 UNDER THE JUDICIALLY CREATED DOCTRINE OF DOUBLE PATENTING OVER CLAIMS 1-22 OF US PATENT 6,027,779, CLAIMS 1-40 OF US PATENT 6,025,044 AND CLAIMS 1-2 OF US PATENT 6,027,811**

The Examiner suggests on page 8 of the Office Action that a terminal disclaimer reciting application serial no. 08/486,963 (rather than the previously submitted terminal disclaimer reciting application serial no. 08/108,963) would be necessary to overcome the double patenting rejection. It is believed that the Examiner intended a terminal disclaimer to application serial no. 08/486,124, now US Patent 6,027,811. Accordingly, a terminal disclaimer to SN 08/486,124 is submitted herewith.

**IV. REJECTION OF CLAIMS 1-5 AND 8-9 UNDER 35 USC 102(b) AS ANTICIPATED BY BUCK et al., US PATENT 4,925,710.**

The Examiner states that Buck et al. disclose a thin-wall non-porous tube comprising porous PTFE and a non-porous coating comprising polymers such as fluorinated ethylene propylene (FEP) and commercially available thermoplastic adhesives such as thermoplastic fluoropolymers. The Examiner further notes that the reference does not disclose the intended use of the PTFE tube as a "catheter balloon" but adds that in the absence of evidence to the contrary or specific structural limitations, the PTFE tube disclosed by the reference anticipates the claim.

As claim 1 is amended herein to specify that the PTFE is porous expanded PTFE having a microstructure of nodes interconnected by fibrils; see Figure 1 and page 7, lines 18-22 for basis. Accordingly, Buck et al. cannot be considered to anticipate the reference.

**V. REJECTION OF CLAIMS 1-9 UNDER USC 103(a) AS UNPATENTABLE OVER BUCK et al. IN VIEW OF GORE, US 3,593,566 AND SOLTESZ, US 5,254,107.**

The Examiner describes that Gore teaches the manufacture of ePTFE and that Soltesz teaches the construction of a tube having a middle layer of wire reinforcement which is enclosed by inner and outer thermoplastic sections wherein the inner section may be PTFE or the like. The catheter tube of Soltesz is expected to be inelastic on the basis of the materials described for use as the Soltesz catheter tube. The claims are rejected as obvious over the combination of the three cited references. In particular, the catheter balloon of claim 7 pertaining to an inelastic balloon is seen as obvious over the inelastic catheter tube of Soltesz.

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Claim 1 as amended herein specifies that the porous expanded PTFE is permeable (please note the Figure 1 schematic of the microstructure of ePTFE indicating nodes interconnected by fibrils; it is apparent that void spaces between adjacent fibrils are interconnected and that consequently the material is porous through its thickness and therefore quite permeable, for example, to gases.

The PTFE tubing of Buck et al. is not taught or suggested to be permeable by any measure. The only porosity of the material of Buck et al. is the result of filling the PTFE with hollow glass microspheres (see Buck et al. at e.g., col 4, lines 48-57). Any void spaces resulting from the filler of spherical glass spheres are contained, with the result that the void spaces cannot be considered to be interconnected and that the tube wall of Buck et al. is not porous through the wall, i.e., the material of the tube wall cannot be considered to be permeable.

The very high flexibility of the catheter balloon of the present invention is the result of the interconnected void spaces of the ePTFE from which it is fundamentally made. It is apparent that the material of Buck et al., having only closed void spaces without any interconnection, cannot be similarly flexible. This concept is analogous to the fact that that closed-cell foams are much more rigid and less flexible than open-cell foams.

Neither Buck et al. nor Soltesz suggest the use of permeable materials having interconnected void spaces (and consequent high flexibility), rendered non-porous through the thickness with a non-porous coating as necessary to enable a balloon to contain pressure. As the materials of both Buck et al. and Soltesz are impermeable to begin with, *there is no reason to combine either Buck et al. or Soltesz with Gore.*

There is simply no suggestion in the art that a catheter balloon might be beneficially made by providing the permeable ePTFE with a non-porous coating. There is no suggestion that a strong, thin, lubricious and highly flexible balloon might be achieved. Accordingly, as amended, claim 1 (and claims dependent thereto) cannot be seen as obvious over the cited references.

#### CONCLUSION

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "Version with markings to show changes made."

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The applicants believe that their claims as amended are in good and proper form and are patentabl over the cited art. As such, the applicants respectfully request reconsideration, allowance of the claims and passage of the case to issuance.

Respectfully submitted,

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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**IN THE CLAIMS:**

Claim 1 has been amended as follows:

1. (Amended). A non-porous catheter balloon comprising permeable, porous expanded polytetrafluoroethylene having a microstructure of nodes interconnected by fibrils and provided with a non-porous coating over the porous expanded polytetrafluoroethylene to render the balloon non-porous], said balloon being collapsible to a small size and inflatable to a maximum diameter].